



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 24, 2014

Tangshan Hongyun Plastic Products Company Limited
C/O Mr. Chu Xiaoan
Room 1606 Bldg. 1 Jianxiang Yuan No. 209
Bei Si Huan Zhong Road
Haidian Distict, Beijing 100083
CHINA

Re: K141878

Trade/Device Name: Hongyun Powder Free Vinyl Patient Examination Gloves

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Gloves

Regulatory Class: I

Product Code: LYZ

Dated: November 5, 2014

Received: November 17, 2014

Dear Mr. Xiaoan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (*if known*)
K141878

Device Name
Hongyun Powder-Free Yellow Vinyl Patient Examination Gloves

Indications for Use (*Describe*)

Powder-Free Yellow Vinyl Patient Examination Gloves is a non sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Type of Use (*Select one or both, as applicable*)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section C

510(k) Summary

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: K141878" (applicant leave blank)

Premarket Notification [510(k)] Summary

[(a)(1)]. The summary contains on the first page, preferably on your letterhead paper, the submitter's name, address, phone and fax numbers, name of contact person, and date the summary was prepared :

Submitter's name : Tangshan Hongyun Plastic Products Co.,ltd
Submitter's address : South Shenggezhuang Village, Pachigang Town, Luannan County, 063502, Hebei Province,China
Phone number : (86)315-4169377
Fax number : (86)315-4169377
Name of contact person: RJ Wang
Date the summary was prepared: 2014-11-05

[(a)(2)]. The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known

Device Name: Powder-Free Yellow Vinyl Patient Examination Gloves
Proprietary/Trade name: "Hongyun Powder-Free Yellow Vinyl Patient Examination Gloves"
Common Name: Patient examination glove
Classification Name: Patient examination glove
Device Classification: I
Regulation Number: 21 CFR 880.6250
Panel: General Hospital (80)
Product Code: LYZ

[(a)(3)]. An identification of the legally marketed device to which your firm is claiming substantial equivalence .

Class I Powder-Free Yellow Vinyl Patient Examination Gloves that meets all of the requirements of ASTM standard D 5250-06 (Reaffirmation 2011).

Predicate device: Powder Free Vinyl Patient Examination Gloves. Colored (Yellow), Hebei Leader Plastic Co., Ltd. K122920.

[(a)(4)] A description of the device

Device Description: Powder-Free Yellow Vinyl Patient Examination Gloves that meets all of the requirements of ASTM standard D 5250-06(Reaffirmation 2011).

-- How the device functions:

PVC films form a barrier to body fluids and bloodborne Pathogens

-- Scientific concepts that form the basis for the device

The PVC rubber is water tight under normal conditions of use. Its tensile properties cause it to conform to the hand, allowing movements necessary for a medical procedure.

-- Physical and performance characteristics such as design, materials and physical properties:

PVC gloves are known to create a barrier to bloodborne pathogens and body fluids. ASTM conforming tensile properties create a glove that is strong and flexible. The glove is manufactured in accordance with the requirements of ASTM D5250 and ASTM D5151 requirements.

[(a)(5)] The summary describes the intended use of the device

Device Intended Use: Hongyun Powder-Free Yellow Vinyl Patient Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

[(a)(6)] A summary of the technological characteristics of new device compared to the predicate device.

The Powder-Free Yellow Vinyl Patient Examination Gloves non sterile are summarized with the following technological characteristics compared to ASTM or equivalent standard.

Features & Description	Predicate Device	Subject Device	Result of Comparison
Company	Hebei Leader Plastic Co., Ltd.	Tangshan Hongyun Plastic Products Co.,ltd	--
510(K) Number	K122920	K141878	
Product name	Powder-Free Vinyl Patient Examination Gloves, Yellow Color	Powder-Free Yellow Vinyl Patient Examination Gloves	Same
Product Code	LYZ	LYZ	Same
Size	Small/ Medium/ Large/X large	Small/ Medium/ Large/X large	Similar
Intend for use	Powder Free Vinyl Patient Examination Gloves. Colored (Yellow) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Powder-Free Yellow Synthetic Vinyl Patient Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Similar
Device Description and Specifications	Meets ASTM D5250-06 (Reapproved 2011)	Meets ASTM D5250 -06 (Reapproved 2011)	Similar
Dimensions -- Length	Meets ASTM D5250-06 (Reapproved 2011) ≥230mm min.	Meets ASTM D5250-06 (Reapproved 2011) 230mm min for all sizes	Similar
Dimensions -- Width	Meets ASTM D5250-06 (Reapproved 2011) Small 80-90 mm Medium 90-100mm Large 100-110mm X large 110-120 mm	Meets ASTM D5250-06 (Reapproved 2011) Small 83-86 mm Medium 94-97 mm Large 104-107mm X large 113-115 mm	Similar
Dimensions -- Thickness	Meets ASTM D5250-06 (Reapproved 2011)	Meets ASTM D5250-06 (Reapproved 2011)	Similar

	Finger 0.05mm min. Palm 0.08mm min.	Finger 0.05mm min. Palm 0.08mm min.	
Physical Properties	Meets ASTM D5250-06 (Reapproved 2011) Before aging/after aging Elongation \geq 300% Tensile Strength \geq 11MPa	Meets ASTM D5250-06 (Reapproved 2011) Before aging/after aging Elongation \geq 300% Tensile Strength \geq 11MPa	Similar
Freedom from Pinholes	Meets <ul style="list-style-type: none"> • 21 CFR 800.20 • ASTM D5250-06 (Reapproved 2011) • ASTM D 5151-06 (Reapproved 2011) 	Meets ASTM D5151-06 (Reapproved 2011) Holes Inspection Level I AQL 2.5	Similar
Residual Powder	Meets ASTM D6124-06 (Reaffirmation 2011)	ASTM D6124-06 (Reaffirmation 2011) Results generated values below 2mg of residual powder	Similar
Compare all materials used to fabricate the devices	PVC	PVC	Similar
Dusting or Donning Powder:	PU	PU	Similar
Dusting or Donning Powder: name	PU	Surface Coating Agent	Similar
Compare performance data supporting substantial equivalence	Meets ASTM D5151-06 (Reapproved 2011) ASTM D5250-06 (Reapproved 2011) ASTM D6124-06 (Reaffirmation 2011)	Meets ASTM D5151-06 (Reapproved 2011) ASTM D5250-06 (Reapproved 2011) ASTM D6124-06 (Reaffirmation 2011)	Similar
Single Patient Use	Single Patient Use	Single Patient Use	Similar
Biocompatibility	SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10:2002/Amd.1:2006	Under the conditions of the study, not an irritant and under conditions of the study, not a sensitizer. SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10 Third Edition 2010-08-01	Similar
Labeling for the legally marketed device to which substantial equivalence is claimed.	-Powder Free -Devices color: Yellow -Patient Examination Glove -Non sterile -Single Use Only - Manufactured For: - Lot	-Powder Free -Devices color: Yellow -Patient Examination Glove -Non sterile -Single Use Only - Manufactured For: - Lot	Similar

[(b)(1)] A brief discussion of the nonclinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence.

Powder-Free Yellow Vinyl Patient Examination Gloves meet requirements per ASTM D5250-06(Reaffirmation 2011), per ASTM D6124-06(Reaffirmation 2011), per 21 CFR 800.20 and ISO 10993-10 Third Edition 2010-08-01.

[(b)(2)] A brief discussion of the clinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence.

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

[(b)(3)] The conclusions drawn from the nonclinical test that demonstrate that the device is as safe, as effective, and performed as well or better than the legally marketed device identified in (a)(3).

It can be concluded that the Powder Free Vinyl Patient Examination Gloves meet the ASTM standard or equivalent standard and FDA requirements for waterleak test on pinhole AQL., meet labeling claims and the Powder-Free Yellow Vinyl Patient Examination Gloves is as safe, as effective, and performs as well as the predicate device Powder Free Vinyl Patient Examination Gloves. Colored (Yellow), Hebei Leader Plastic Co., Ltd. K122920.